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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,128	11/27/2001	Alan N. Houghton	MSK.P-026-3	3698

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,128	HOUGHTON ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 5, 10-12, 17 and 19-24, drawn to a method for treating melanoma in a mammalian subject, comprising the step of administering to the subject an immunologically-effective amount of a xenogeneic differentiation antigen, wherein said antigen is human tyrosinase, classified in class 514, subclass 8. Claims 1, 4, 10, 11, 17, 20, 23 and 24 will be examined with this Group to the extent that the xenogeneic differentiation antigen is a human tyrosinase.

II. Claims 1, 3, 4, 6, 10, 11, 13, 19, 20, 23 and 24, drawn to a method for treating melanoma in a mammalian subject, comprising the step of administering to the subject an immunologically-effective amount of a xenogeneic differentiation antigen, wherein said antigen is human gp75, classified in class 436, subclass 64. Claims 1, 4, 10, 11, 19, 20, 23 and 24 will be examined with this Group to the extent that the xenogeneic differentiation antigen is a human gp75.

III. Claims 1, 7-11, 14, 15, 18-20, 23 and 24, drawn to a method for treating melanoma in a mammalian subject, comprising the step of administering to the subject an immunologically-effective amount of a xenogeneic differentiation antigen, wherein said antigen is a murine tyrosinase, classified in class 424, subclass 184.1. Claims 1, 4, 7-10, 11, 14, 19, 20, 23 and 24 will be examined with this

Group to the extent that the xenogeneic differentiation antigen is a murine tyrosinase.

IV. Claims 1, 7-10, 14, 16, 19, 20, 23 and 24, drawn to a method for treating melanoma in a mammalian subject, comprising the step of administering to the subject an immunologically-effective amount of a xenogeneic differentiation antigen, wherein said antigen is murine gp75, classified in class 424, subclass 184.1. Claims 1, 7-10, 14, 19, 20, 23 and 24 will be examined with this Group to the extent that the xenogeneic differentiation antigen is a murine gp75.

V. Claims 26, drawn to a vector comprising SEQ ID NO: 1, classified in class 435, subclass 320.1.

VI. Claim 27, drawn to a vector comprising SEQ ID NO: 2, classified in class 435, subclass 320.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vector of Group V, which encodes the human tyrosinase

implemented in the *in vivo* method of Group I could also be used in an *in vitro* reporter assay.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vector of Group VI, which encodes the murine tyrosinase implemented in the *in vivo* method of Group II could also be used in an *in vitro* reporter assay.

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of all four groups read on a method of treating melanoma comprising administering a xenogeneic differentiation antigen. However, each differentiation antigen is patentably distinct and structurally different and would elicit a different immune response. Groups I-IV use the differentiation antigens, human tyrosinase, human gp75, murine tyrosinase and murine gp75, respectively.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups V

and VI both are both vectors, which comprise polynucleotide sequences, however the sequences are distinct and encode structurally different proteins.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Marina Larson on June 24, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, but can normally be reached between the hours of 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Y. Chan can be reached on (703)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
17 June 2004